DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 20, 2015

ArraVasc Limited
c/o Jan-Paul van Loon
Qserve Group US Inc.
P.O Box 940
Charlestown, NH 03603

Re: K151153
Trade/Device Name: Pirouette 018
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: July 9, 2015
Received: July 13, 2015

Dear Jan-Paul van Loon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151153

Device Name
Pirouette 018

Indications for Use *(Describe)*
Pirouette 018 is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal and renal arteries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Submitter

Submitter Address:	ArraVasc Limited 2 Ballybrit Business Park, Galway Ireland
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Contact Person:	Máiréad McCaffrey
Date Prepared:	15 April 2015

2. Device

Device Trade Name:	Pirouette 018
Common Name:	OTW PTA catheter
Classification Name:	Peripheral Transluminal Angioplasty Catheter
Classification number:	21 CFR 870.1250
Product code:	LIT
Class:	II
Classification Panel:	Cardiovascular

3. Predicate Devices

Primary predicate:	Bantam and Bantam Ŭ OTW PTA Catheter Clearstream Technologies Ltd. 510(K) number: K112335/K093139
Secondary predicate:	SABER™ PTA Dilation Catheter Cordis Corporation 510(K) number: K133843

4. Device Description

Device Description:	The Pirouette 018 Percutaneous Transluminal Angioplasty (PTA) Catheter Family are standard over the wire (OTW), semi-compliant, coaxial design catheters with a balloon mounted on the distal tip. The distal portion of the catheter has a hydrophilic coating. The manifold connector and shaft design consists of a guidewire lumen allowing the catheter to track over a guidewire and an inflation lumen, used to inflate and deflate the balloon. Radiopaque markers are positioned on the shaft within the balloon to enable visualisation of the catheter/balloon under fluoroscopy. The catheter is compatible with .018 inch (0.46 mm) wire guides. The Pirouette 018 PTA Catheter Family includes multiple balloon sizes ranging from 2 to 9 mm in diameter and 20 to 300mm in length. The nominal balloon diameter (mm) and the balloon length (mm) are inscribed on the guidewire hub of the manifold. The effective lengths of the balloon range from 45cm to 150cm.
Physical Description:	Percutaneous Transluminal Angioplasty Catheter (PTA Catheter).

5. Indication for use

Indications for Use Statement:	Pirouette 018 is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal and renal arteries.

6. Comparison of technological characteristics with the predicate device

Summary of Technological Characteristics	The Pirouette 018 incorporates substantially equivalent design, packaging, fundamental technology, materials, manufacturing, sterilization and intended use as those featured in the primary predicate Bantam and Bantam Ŭ OTW PTA catheters and contains a hydrophilic coating substantially equivalent to the secondary predicate SABER™ PTA catheter.

Table 1 Summary of general and technical characteristics against the predicate devices.

Parameter	Characteristics
Classification	Class II, 21 CFR 870.1250 Same Classification as predicate devices.
Intended Use	Same intended use of balloon dilatation of the femoral, popliteal and infra-popliteal arteries with additional vessels; iliac and renal indicated.
Balloon material	Same type of material
Balloon diameter	Same range of balloon diameters: 2 - 9 mm
Balloon length	Comparable range of balloon lengths: 20 - 300mm
Nominal pressure (atm)	Same or higher nominal pressure: 8 atm.
Rated burst pressure (atm)	Comparable rated burst pressure: 16atm (2.0-5.0mm balloon diameter) / 14atm (6.0mm balloon diameter) / 12atm(7.0-9.0mm balloon diameter)
Radiopaque Marker bands	Two Markerbands, one at distal and one at proximal side of the balloon, with the same function.
Outer shaft	Same type material
Catheter shaft outer diameter	Same diameter or lower: 3.6 ï 4.2 Fr
Catheter Usable Lengths (cm)	Comparable range of usable lengths: 45 - 150cm
Recommended Introducer Sheath compatibility	Comparable size or lower: 4 ï 5 Fr
Recommended Guidewire diameter	Same compatibility; maximum 0.018ò
Catheter strain relief & manifold material	Same type of material, with the same function.
Catheter manifold design	Same design, dual lumen Y design, with the same function.
Catheter coating	Similar type of coating.
Sterilization Method	Same method; Ethylene Oxide.
Single Use / Reusable	Single Use

7. Performance Data

The Pirouette 018 was thoroughly tested on the bench to evaluate and verify that it meets the required performance specifications and to support a determination of substantial equivalence. The bench testing plan was developed with the consideration of the recommendations outlined in the applicable FDA guidance documents, tests recommended in ISO 10555-1, Intravascular catheters- Sterile and single-use catheters - Part 1: General Requirements, and 10555-4, Intravascular catheters- Sterile and single-use catheters - Part 4: Balloon dilatation catheters. Testing performed on the Pirouette included the following:

Non-Clinical Tests:

- Dimensional verification
- Balloon preparation, pushability , trackability, deployment,withdrawal and balloon reinsertion
- Balloon rated burst pressure (RBP)
- Balloon fatigue (repeated balloon inflations)
- Balloon Compliance at nominal and rated burst inflation pressure
- Balloon Inflation/Deflation Time
- Catheter Bond Strength (Tip to balloon, balloon to proximal shaft, shaft to manifold)
- Flexibility and Kink test
- Torque Strength
- Radiopacity
- Coating Integrity
- Particulate evaluation
- Guide wire compatibility
- Introducer sheath compatibility

The results showed that the Pirouette 018 met the pre-determined acceptance criteria.

Biocompatibility Tests:

Per ISO10993-1:2009, *Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process,* the Pirouette 018 is classified as an externally communicating device, which contacts circulating blood during a limited contact duration (Ò24hours). Biocompatibility testing conducted on Pirouette 018 per ISO 10993-1:2009 included the following:

- MTT Cytotoxicity Study
- ISO Maximization Sensitization Study
- ISO Intracutaneous Study
- ISO Systemic Toxicity Study
- ASTM Hemolysis
- C3a Complement Activation Assay
- SC5b-9 Complement Activation Assay
- ASTM Partial Thromboplastin Time
- In Vivo Thromboresistance Study - Jugular Vein
- Pyrogenicity

The test results show that the Pirouette 018 is biocompatible.

Sterilization, Shelf life tests and Packaging validation:

- EtO sterilzation validation
- EtO/ECH residue determination
- Shelf life testing
- Packaging validation

Test results show that the Pirouette 018 is sterile and sterility is maintained by the packaging during the entire shelf life of the device. From the results it was also concluded that the device meets the criteria for Residual Testing, i.e. EtO/ECH residues.

Clinical Performance Data:

- No clinical studies were performed for the purpose of obtaining safety and effectiveness data.
- The Pirouette 018 has been approved for marketing in the European Union (CE certified) in 2014, and has been marketed in the EU for since then.

8. Conclusions

The performance testing presented above establishes that the Pirouette 018 is as safe and effective for its intended use as the predicate device. The comparison tabulated above demonstrates that the Pirouette 018 device is substantially equivalent to the predicate devices.

Information contained within this submission demonstrates that the Pirouette 018:

- Has legally marketed predicate devices;
- Has identical indications for use as the identified primary predicate devices;
- Incorporates the same fundamental technology, and uses accepted scientific methods and international standards to evaluate device safety and effectiveness;
- Demonstrates that the design and performance of the Pirouette 018 has equivalent safety and performance characteristics of predicate devices, and does not raise different questions of safety and effectiveness.

Based upon the; intended use, design, performance characteristics, non-clinical performance testing performed, and comparison to legally marketed devices, it is concluded that the Pirouette 018 is appropriate for its intended use, and is substantially equivalent to the predicate devices.